REMARKS

Claim Rejections:

Definiteness Rejections

The Examiner rejects claims 131, 137, and 139 on page 2 of the Office Action on indefiniteness grounds. Applicants amend the claims 131, 137 and 139 as suggested by the Examiner.

Anticipation Rejections

On pages 3-4, item 8 of the Office Action, the Examiner rejected the claims 139-141 and 147-149 alleged being anticipated by Hyon *et al.* The Examiner specifically states that "Hyon discloses a method for making a cross-linked UHMWPE, which includes all limitations recited in the claims." Applicants respectfully disagree with the Examiner and note that:

In order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. See Scripps Clinic & Research Foundation v. Genentech, Inc., 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986); see also MPEP § 2131. Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01. Claims are to be given their broadest reasonable interpretation consistent with Applicants' specification. See In re Zletz, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow); MPEP § 2111.

Not only must the claim terms, as reasonably interpreted, be present, an allegedly anticipatory reference must enable the person of ordinary skill to practice the

invention as claimed. Otherwise, the invention cannot be said to have been already within the public's possession, which is required for anticipation. See Akzo, N.V. v. U.S.I.T.C., 1 USPQ2d 1241, 1245 (Fed. Cir. 1986); In re Brown, 141 USPQ 245, 249 (CCPA 1964).

Applicants provides the following arguments to overcome the 35 USC § 102 rejections:

Hyon does not teach the claimed invention because Hyon does not disclose (1) heating of polyethylene below the melt prior to irradiation or (2) a cross-linked polyethylene having multiple melting peaks

The Examiner states that according to Hyon et al., "[t]he heat generated (by irradiation at the provided temperatures listed in col.3, lines 44-46) is sufficient to cross-link and at least partially melt the UHMWPE (col.3, lines 47-65; col.4, lines 4-16)." The Applicants point out that the temperatures disclosed by Hyon at col.3, lines 44-46 is the atmospheric temperature rather than the temperature of the polyethylene and is not sufficient enough to support melting of the polyethylene by subsequent irradiation. Yet the temperature in the later passages are used in molding of the crosslinked polyethylene after irradiation, and does not concern the temperature of polyethylene during irradiation.

Claims 139-141 describe methods of making a crosslinked polyethylene by irradiating at various temperatures, thereby generating sufficient heat from the irradiation to at least partially melt the polyethylene, and then cooling heated the polyethylene. During irradiation, specifically at the beginning of irradiation, the polyethylene is at that temperature. In contrast, Hyon describes the temperature of the atmosphere that might surround the polyethylene during irradiation to have a certain temperature. Considering the fact that polyethylene has a very low thermal conductivity, the size of the specimens described in the present application would take

a considerable amount of time to achieve a uniform temperature throughout. For instance, to heat a polyethylene having 4cm thickness and 10 cm diameter to 90°C, it would take over one hour to achieve uniform temperature throughout. Hyon (col 3, line 44) does not describe heating the polyethylene, but simply heating the atmosphere around the polyethylene. Also Hyon advocates the use of low radiation dose levels. If one analyzes the equation in the application on page 23, one would realize that in low dose levels the partial melting of polyethylene would be minimal. Specifically if the irradiation temperature is room temperature there will be no melting at the dose levels of Hyon *et al.* If the temperature is above 90°C, and if the radiation is not carried out at very high dose rate using a powerful electron beam, there again will not be sufficient heating of the parts associated with the radiation. This is because during irradiation some of the heat generated is lost to the surroundings if the irradiation is not carried out fast enough. This will be a non-adiabatic condition and it will result in no appreciable increase in the temperature of the polyethylene. For instance, if one uses gamma irradiation and keeps the radiation dose level below 5 Mrad (as in Hyon *et al.*), the extent of heating even at 90°C, will be low.

Regarding claim 147, the Examiner states that the "Hyon discloses a method for making a cross-linked polyethylene comprising the steps providing polyethylene at a temperature below the melting point (col.3, lines 44-46), irradiating to cross-link and generate heat to at least partially melt polyethylene (col.3, lines 32-67), and cooling the polyethylene (col.4, lines 44-45)." In response, the Applicants point out that Hyon does not disclose a method of providing the polyethylene at a higher temperature (that is, pre-heating of polyethylene below the melting point before irradiation) and then irradiating at the elevated temperature to generate sufficient heat to at least partially melt the polyethylene for reasons described in the above paragraph.

Hyon does not teach the claimed invention because UHMWPE does not melt at 80°C

The Examiner states on page 4 of the Office Action that "Hyon *et al.* discloses an irradiation temperature, which would melt the polyethylene (col.3, lines 39-65)." In response, Applicants respectfully disagree with the Examiner's interpretation of the reference. Applicants point out that the "col. 3, lines 39-46" indicates a temperature of 80°C, which is well below the melting point of UHMWPE. The melting point of UHMWPE is about 137°C. Applicants further point out that claim 148 recites that "the irradiation melts the polyethylene." Because, the polyethylene is pre-heated below melting point, which facilitated melting during subsequent irradiation. Hyon does not teach an irradiation process that melts polyethylene. Rather, according to Hyon *et al.*, "cross-linked molded article is heated up to a compression-deformable temperature [ ] preferably 180° to 200° C to melt completely." See Hyon *et al.*, col.4, lines 4-12.

Hyon does not teach further heating of partially melted polyethylene following irradiation

The Examiner stated that "Hyon discloses further heating of the polyethylene (col.4, lines 4-16, 57-60)." Applicants respectfully disagree with the Examiner's interpretation of the Hyon-disclosure and point out that Hyon does not heat polyethylene prior to irradiation. Therefore, there is no step of further heating of the polyethylene. That is, Hyon does not teach an additional source to heat the polyethylene.

Therefore, the Examiner has failed to demonstrate that each and every claim term is contained in a single prior art reference. For further clarity, Applicants amend claims 139-141 and 147 by more clearly describing the heating step prior to irradiation. Applicants respectfully request the withdrawal of the rejections.

Obviousness Rejections

On pages 4-9, items 9-16 of the Office Action, the Examiner rejected: claims 124, 126-127, 129, 132, and 134-135 as obvious over Hyon *et al.* in view of Howard, Jr. *et al.*; claim 130 as obvious over Hyon *et al.*; claims 125 and 133 as obvious over Hyon *et al.* in view of Howard, Jr. *et al.* as applied to claim 124 and 132, respectively, and further in view of Bashir et al.; claim 128 as obvious over Hyon *et al.* in view of Howard as applied to claim 124 and further in view of Dearnaley *et al.*; 131 and 136 as obvious over Hyon *et al.* in view of Howard as applied to claim 124 and 132, respectively, and further in view of Parikh *et al.*; claims 137-138 as obvious over Sun *et al.* in view of Howard, Jr. *et al.*; claim 142 as obvious over Sun *et al.* in view of Rose *et al.;* claim 143 as obvious over Sun *et al.* in view of Rose *et al.* and further in view of Hyon *et al.;* claim 144 as obvious over Dearnaley *et al.* in view of Howard, Jr. *et al.*; and claims 145-146 as obvious over Dearnaley *et al.* in view of Rose *et al.*

In response, Applicants respectfully traverse the rejections and refer the arguments of the above paragraphs made in order to obviate the alleged §102 rejections. As indicated above, Hyon *et al.* do not disclose or suggest each and every claim term of the instant invention, thus, any combination with Hyon *et al.* is improper. In view of the above argument, Applicants further point out that Howard, Jr. *et al.* (US patent No. 5,684,124); Bashir *et al.* (US Patent No. 5,001,206); Dearnaley *et al.* (US Patent No. 5,593,719); Parikh *et al.* (US Patent No. 6,005,053); Sun *et al.* (US patent No. 6,174,934); and Rose *et al.* do not rectify the deficiencies in Hyon *et al.*

At the outset, Applicants note the examiner must show all of the recited claim elements in the combination of references that make up the rejection. When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable

expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* MPEP §§ 2142-43 (August 2001). Thus, the examiner must provide evidentiary support based upon the contents of the prior art to support all facets of the rejection, rather than just setting forth conclusory statements, subjective beliefs or unknown authority. *See In re Lee*, 277 F.3d 1338, 1343-44 (Fed. Cir. 2002).

When an examiner alleges a *prima facie* case of obviousness, such an allegation can be overcome by showing that (i) there are elements not contained in the references or within the general skill in the art, (ii) the combination is improper (for example, there is a teaching away or no reasonable expectation of success) and/or (iii) objective indicia of patentability exist (for example, unexpected results). *See U.S. v. Adams*, 383 U.S. 39, 51-52 (1966); *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923, 1927 (Fed. Cir. 1990); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 230 USPQ 416, 419-20 (Fed. Cir. 1986). Applicants submit that the rejections do not meet this test.

Applicants further explain that:

Hyon's method is limited to 5 Mrads dose and does not result in polyethylene with multiple melting peaks

Referring to claim 124, Hyon does not disclose the polyethylene treated with radiation having crosslinks and multiple melting peaks. Hyon's method does not, inherently, result in polyethylene with multiple melting peaks. Irradiation of polyethylene in an atmosphere that is kept at 90°C with a radiation dose level of 5Mrad with or without subsequent heat treatment will not result in multiple melting peaks. In order to achieve multiple melting peaks, one would have to use a radiation dose level more than

5Mrad and at an elevated temperature to achieve multiple melting peaks. None of these conditions are disclosed by Hyon. In view of the melting peaks described in Howard, the two melting peaks achieved by his method are possible through a high pressure crystallization of the polymer. This manipulation of the material to achieve two melting peaks using high pressure crystallization results in an increased cystallinity of the polymer. In stark contrast, the instant methods result in multiple melting peaks, yet with lower crytallinity than the starting material. In fact, it is desirable to achieve lower crytallinity and not higher crytallinity for many medical device applications. The teachings of Howard have led to the development of medical devices, one under the trade name of Hylamer, which showed extensively higher wear rates as compared to the starting materials. Therefore, it would not have been obvious to one having ordinary skill in the art, at the time the invention was made, to combine Howard's teachings of multiple melting peaks manipulation. The combination would result in inferior material in terms of wear resistance.

Referring to claim 125 and 132, neither Hyon nor Howard disclose a cross-linked polyethylene with three melting peaks. Bashir teaches a polyethylene with three melting peaks achieved by blending different polyethylene types. This is done in order to optimize mechanical properties of the blend. Applicants' invention, however, is something different from Bashir's blend.

Referring to claim 128, Applicants point out that the polymer structure in extensively crosslinked so that a substantial portion of it does not dissolve in hot xylene. Applicants further point out that the instant application does not concern the use of DECALIN or xylene extraction to improve the wear resistance of UHMWPE, like Dearnley does (see specification page 27, lines 15-22; page 35, lines 13-29). Claim 128 recites a property of the radiation and heat treated polyethylene in that such

polyethylene does not dissolve in DECALIN or xylene under conditions set forth, which is a test evaluating cross-linking.

Referring to claim 131 and 136 Hyon does not disclose a polyethylene with a tensile modulus less than 940 MPa and crystallinity less than 50%. In fact the material that Hyon is describing, because it is oriented after irradiation, will have a tensile modulus much higher than 940 MPa. Similarly Howard discloses a material with increased crystallinity which would result in an increased tensile modulus. Therefore, Howard's material will have a crystallinity, above 55% (in fact closer to 70%) and a modulus that is about 1200 MPa or above.

Sun does not teach heating the polyethylene before irradiation

Referring to claim 137 and 138, Sun does not disclose heating the polyethylene before irradiation. The instant invention provides for the heating of polyethylene before the irradiation, which is necessary to achieve the partial melting during irradiation *vis-a-vis* the equation on page 23 of the application. In col 5, lines 55-57, Sun disclose the temperature at which the polyethylene is heated after irradiation. The instant invention teaches the heating of polyethylene before irradiation.

Sun's method does not provide polyethylene with free radicals below the detection limit of ESR and Rose's method does not reduce wear

Referring to claim 142, Sun disclosed heating the irradiated polyethylene to a temperature below its melting temperature (col 5, lines 55-57). The heating after irradiation disclosed by Sun et al. will only reduce the free radicals but not lead to an undetectable level of free radicals. The instant invention discloses heating above the melting point to reduce the concentration of free radicals to below the detection limit of electron spin resonance.

Claim 15 of Sun claims free radical concentration less that 10^{17}/g, which is a concentration of free radicals that is detectable. The detection limit of ESR is 10^{14}/g. The UHMWPE described in the claim 142 can have free radicals less than 10^{14}/g, which is not detectable by ESR. This is only possible to achieve if the irradiated polyethylene is heated to above its melting point, which is not within Sun's teachings.

Rose describes the use of high radiation dose levels and shows that wear increases with this irradiation, unlike what the Examiner has stated that "irradiation [ ] improves cross-linking without increasing wear" (see page 393, Abstract lines 10-11).

The combination of Rose and Sun would lead to a radiation crosslinked UHMWPE with residual free radicals at a detectable level. The instant invention provides a radiation treated UHMWPE (with more than 5 Mrad, for example) with substantially no detectable free radicals.

Referring to claim 143, the final temperature of the polyethylene at the end of the irradiation is above the melting point of the polyethylene. The polyethylene referred to in 142 is provided at a pre-heated temperature below its melting point. It is then irradiated and the irradiation induced heating melts the polyethylene. The partial melting is induced by irradiation. For further clarify, Applicants amend claim 142 by more clearly describing the heating step prior to irradiation.

Claims 142 and 143 refer to a dose level above 5Mrad, which are outside the ranges of Hyon. Hyon specifically teaches to stay below 5Mrad. Sun discloses heating the irradiated UHMWPE to a temperature that is below its melting temperature (see col.4, lines 38-47), unlike the instant invention. Again Rose teaches that wear increases with increasing radiation dose level unlike what the Examiner has stated that "irradiation [ ] improves cross-linking without increasing wear" (see page 393, Abstract lines 10-11).

Howard and Dearnaley do not teach the claimed invention because there is no known correlation between mechanical properties and wear resistance, as speculated by the Examiner.

There is no teaching in Howard that leads to low wear because the mechanical properties are improved. The Examiner is assuming that by improving mechanical properties, whatever they may be, the wear resistance of polyethylene would increase. The material disclosed by Howard, however, is known to have higher wear than conventional polyethylene *in vivo* (see above).

Referring to the instant claims 145 and 146, unlike what the Examiner has speculated, Dearnaley does not disclose irradiation of polyethylene at a temperature above room temperature (col.4, lines 32-39). Dearnaley teaches performing the extraction of low molecular weight species in a hot solvent, *i.e.,* at above room temperature. Rose *et al.* disclose that higher radiation dose levels increase wear of UHMWPE (see Fig. 3 and the abstract of Rose *et al.*). According to Rose *et al.* "Wear generally increased with dosage and contact stress" (see line 4 in the abstract of Rose *et al.*). Thus, Rose *et al.* teach away from the instant invention, at least in regard to the effect of radiation on susceptibility to wear. Therefore any combination of Dearnaley *et al.* and Rose *et al.* is improper and will not make the instant invention obvious.

It is, therefore, clear from the above arguments and the facts that the Examiner has failed to set forth a *prima facie* case of obviousness. Withdrawal thereof is respectfully requested.

Conclusion

In view of this Amendment and Applicants' remarks above, Applicants respectfully submit that the application is in condition for allowance. If any additional fees or additional extensions of time are required with the filing of this Amendment, Applicants respectfully request such fees and extensions be charged to Deposit Account No. 08-1641.

Respectfully submitted,

9-18-02
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MARKED UP COPY OF AMENDMENTS

In the Specification:

Title of Table 18 on page 62:

Table 18: WIR-AM GUR 4050 **[barstock]** **bar stock**, Total dose =140 kGy, 75 kGy/pass

Title of Table 19 on page 67:

Table 19: WIR-AM GUR 1050 **[barstock]** **bar stock**, Total dose = 150 kGy, 75 kGy/pass

In the Claims:

131. (once amended) The **medical** prosthesis of claim 124, wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity and less than about 940 MPa tensile elastic modulus, so as to reduce production of fine particles from said prosthesis during wear of said prosthesis.

137. (once amended) A method for making a cross-linked ultra high molecular weight polyethylene having multiple melting peaks, comprising the steps of: **[providing]** **heating** ultra high molecular weight polyethylene having polymeric chains **to a temperature below the melting point of the polyethylene**; irradiating said ultra high molecular weight polyethylene so as to cross-link said polymeric chains; and cooling said **[heated]** **irradiated** ultra high molecular weight polyethylene.

139. (once amended) A method for making **a_cross-linked** ultra high molecular weight polyethylene, comprising the steps of: **[providing] heating** ultra high molecular weight polyethylene having polymeric chains **[that is at room temperature or below room temperature] to a temperature below the melting point of the polyethylene**; irradiating said ultra high molecular weight polyethylene so as to (1) cross-link said polymeric **[chairs] chains** and (2) to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene; and cooling said **[heated] irradiated** ultra high molecular weight polyethylene.

140. (once amended) A method for making cross-linked ultra high molecular weight polyethylene, comprising the steps of: **[providing] heating** ultra high molecular weight polyethylene **[at] to** a temperature of no more than about 90°C; irradiating said ultra high molecular weight polyethylene to cross-link the ultra high molecular weight polyethylene and to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene; and cooling said irradiated ultra high molecular weight polyethylene.

141. (once amended) A method for making cross-linked ultra high molecular weight polyethylene, comprising the steps of: **[providing] heating** ultra high molecular weight polyethylene at a temperature ranging from about 90°C to below the melting point; irradiating said ultra high molecular weight polyethylene to cross-link the ultra high molecular weight polyethylene and to generate sufficient heat to at least partially melt the ultra high molecular weight polyethylene; and cooling said irradiated and heated ultra high molecular weight polyethylene.

142. (twice amended) A method for making a cross-linked ultra high molecular weight polyethylene having substantially no detectable free radicals, comprising the steps of: **[providing] heating** ultra high molecular weight polyethylene having polymeric chains

to a temperature below the melting point of the polyethylene[, wherein the ultra high molecular weight polyethylene is at a temperature below its melting point]; irradiating said ultra high molecular weight polyethylene with more than 5 Mrads of radiation so as to cross-link said polymeric chains, wherein the radiation heats the ultra high molecular weight polyethylene; and cooling said heated ultra high molecular weight polyethylene.

147. (twice amended) A method for making a cross-linked polyethylene, comprising the steps of: **[providing] heating** polyethylene at a temperature that is below its melting point; irradiating the polyethylene so as to (1) cross-link polymeric chains in the polyethylene and (2) to generate sufficient heat to at least partially melt the polyethylene; and cooling the **[heated] irradiated** polyethylene.